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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,609	07/25/2003	Etsuko Matsunaga	240944US0	9357

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EXAMINER	
FOX, DAVID T	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,609	MATSUNAGA ET AL.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/23/05 & 2/23/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 February 2006, and Applicant's amendment of 23 December 2005, have been entered.

Applicant's amendments and accompanying arguments of 23 December 2005 have overcome all rejections of record. The instant Examiner concurs that the previously cited art does not teach or reasonably suggest a method of selecting transformed plant cells on a medium comprising an auxin precursor, followed by whole plant regeneration therefrom, as argued by Applicant. Furthermore, a lack of reasonable expectation of success is further evidenced by the new grounds of rejection under 35 USC 112, first paragraph, as set forth below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 25, and dependents, are indefinite for failing to consistently recite required claim elements throughout the claim. In claim 6, the required claim element of a desired polynucleotide sequence is recited in part (A) only. In claim 25, the preamble recites a vector for inserting a desired gene into a plant, while the body of the claim

recites a vector for inserting a desired polynucleotide into a plant. The following amendments would obviate this rejection. All amendments must comply with 37 CFR 1.121(c).

In claim 6, part (D), insert the following phrase before the period:

---comprising said desired polynucleotide sequence---.

In claim 25, line 1, replace "gene" with ---polynucleotide---.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-11 and 13-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method for transforming a plant cell with a vector comprising any selectable marker gene of any sequence and from any source, encoding any enzyme which somehow synthesizes auxin from an auxin precursor. Claim 13 is broadly drawn to the above method wherein the vector additionally comprises any "cytokinin synthesis gene" of any sequence and from any source, which encodes any gene product of any sequence which is somehow involved in cytokinin synthesis.

In contrast, the specification only provides guidance for plant transformation with a vector comprising the *iaaH* gene encoding the enzyme indoleacetamide hydrolase as the auxin biosynthesis gene, and the *ipt* gene encoding the enzyme isopentenyl transferase as the cytokinin biosynthesis gene, wherein both genes are from the bacterial species *Agrobacterium tumefaciens*. No guidance is presented for the identification of any other protein sequence from any other source which is involved in auxin or cytokinin synthesis, or for the identification or characterization of any nucleotide sequence encoding said multitude of proteins.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claims 6-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a method for producing a transgenic plant comprising transforming a plant cell with an *iaaH* gene and an *ipt* gene,

culturing the plant cell on a medium comprising indoleacetamide or naphthalene acetamide, selecting transformed plant cells based on their ability to produce shoots on said medium, and regenerating a whole transformed plant therefrom; does not reasonably provide enablement for claims broadly drawn to the use of any gene encoding any enzyme which synthesizes an auxin from any auxin precursor, the use of any non-exemplified auxin precursor as a selection agent, the use of an *iaaM* gene, or the omission of the *ipt* gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for transforming a plant cell with a vector comprising any selectable marker gene of any sequence and from any source, encoding any enzyme which somehow synthesizes auxin from an auxin precursor, wherein viable and regenerable transformed plant cells are selected. Claim 13 is broadly drawn to the above method wherein the vector additionally comprises any "cytokinin synthesis gene" of any sequence and from any source, which encodes any gene product of any sequence which somehow is involved in cytokinin synthesis. The claims are also broadly drawn to the use of any auxin precursor as a selection agent.

In contrast, the specification only provides guidance for plant cell transformation with a vector comprising the *iaaH* gene encoding the enzyme indoleacetamide hydrolase as the auxin biosynthesis gene, and the *ipt* gene encoding the enzyme isopentenyl transferase as the cytokinin biosynthesis gene, wherein both genes are from the bacterial species *Agrobacterium tumefaciens*. Moreover, the specification only

provides guidance for the selection of transformed plant cells on a medium containing indoleacetamide or naphthalene acetamide. No guidance is presented for the identification of any other protein sequence from any other source which is involved in auxin or cytokinin synthesis, for the identification or characterization of any nucleotide sequence encoding said multitude of proteins, or for the use of other auxin precursors as selection agents. Furthermore, no guidance is provided for selecting viable and regenerable plant cells when using non-exemplified genes encoding non-exemplified auxin or cytokinin synthesis enzymes, or when omitting the cytokinin synthesis enzyme-encoding gene.

The use of auxin precursors as selection agents, and the use of exemplified or non-exemplified genes encoding enzymes involved in auxin synthesis as selectable marker genes, for the selection of viable and regenerable plant cells is unpredictable. Budar et al (1986, previously cited) teach that the presence of "gene 2" (or the *iaaH* gene) prevents whole plant regeneration on medium containing the auxin precursors naphthalene acetamide or indole-3-acetamide (see, e.g., page 202, column 1, bottom two paragraphs, column 2, top paragraph). Prinsen et al (Applicant submitted) teach that the presence of another auxin biosynthesis gene, namely "gene 1" encoding IAM synthase, inhibited tissue growth and caused tissue death (see, e.g., page 73, paragraph bridging the columns). Sitbon et al (1992, Plant Physiology), teach that the presence of both the *iaaM* and *iaaH* gene results in abnormal plant physiology, including retarded growth and development (see, e.g., page 1062, Abstract). Depicker et al (Applicant submitted) teach that the *iaaH* gene is ineffective as a positive

selectable marker when transformed plant cells are cultured on medium containing low levels of naphthalene acetamide, due to leakage into the growth medium of the auxin NAA produced by transgenic cells (see, e.g., paragraph bridging pages 64 and 65).

Furthermore, the use of non-exemplified genes encoding non-exemplified auxin synthesis enzymes is unpredictable. Spena et al (1991, Molecular and General Genetics) teach that plant transformation with a gene encoding the enzyme indoleacetic acid-lysine synthase results in leaf epinasty and decreased root growth (see, e.g., page 205, Abstract). Schmulling et al (1988, The EMBO Journal) teach that plant transformation with the *Agrobacterium rhizogenes*-derived *rolB* and *rolC* genes resulted in dwarfism, male sterility, reduced female fertility, necrosis of callus and leaves, and failure of callus to regenerate shoots (see, e.g., page 2622, column 2, penultimate paragraph; page 2623, column 2, second paragraph; page 2625, column 1, bottom paragraph and column 2, penultimate paragraph; page 2627, column 1, Table 1). Estruch et al (1991, The EMBO Journal) teach that the *rolB* gene encodes an indole glucoside hydrolase, i.e. an enzyme involved in the synthesis of auxin from an auxin precursor (see, e.g., page 3125, Abstract).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate vectors comprising a multitude of exemplified or non-exemplified genes encoding a multitude of exemplified or non-exemplified auxin synthesis or cytokinin synthesis enzymes, for their ability to act as positive selection markers for the selection of regenerable transformed plant cells. Furthermore, undue experimentation

would have been required to evaluate the ability of a multitude of non-exemplified auxin precursors to act as selection agents. Finally, undue experimentation would have been required to obtain successful selection of viable and regenerable transformed plant cells in the presence of the *iaaM* gene and in the absence of the *ipt* gene.

The claims are deemed free of the prior art, as stated above.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1600 1638

April 26, 2006